

PAIN RELIEVING COLD THERAPY- menthol gel
AHC VENTURES CORP DBA CRYODERM

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pain Relieving Cold Therapy

Active Ingredient

Menthol USP 10.0%

Purpose

Pain Reliever

Uses

Temporarily relieves minor minor aches and pains associated with

- sore muscles and joints
- arthritis
- backache
- muscle strains
- sprains
- bruises

Warnings

For external use only

When using this product

Use only as directed

Do not bandage or cover the area being treated

Do not apply ice or heating pad in conjunction with this product

Do not use with any medical device or any other device

Do not combine with any other topical treatments

Avoid contact with eyes or mucous membrane

Do not apply to wounds or damaged skin

Stop use and ask a doctor if:

Conditions worsens or symptoms persist for more than 7 days or clear up and recur

- Redness if present or irritation develops

If Pregnant or Breast Feeding

Ask a healthcare professional before use

Keep Out of Reach of Children

In case of accidental ingestion get medical help or contact a Poison Control Center immediately

Directions - Adults and children 2 years of age and older

Massage a liberal amount of gel directly on the skin over the affected area

- Repeat as necessary but do not apply more than 4 times daily

Children under 2 years of age: Consult a physician

Other information

Store in a cool dry place with lid or cap closed tightly

Flammable: Keep away from excessive heat or open flame

Inactive Ingredients

Acrylates, Arnica, Boswella Serrata, Eucalyptus Oil, Glycerin, Ilex Paraguariensis Leaf Extract, Dimethyl Sulfone(MSM), Peppermint Oil, Purified Water, SD Alcohol 39-C, Triethanolamine

PDP

CryoDerm

Pain Relieving Cold Therapy

Gel

Fast Acting, Penetrating Pain Relief For:

Muscle Strains, Joint Pain, Backache, Arthritis, Sprained Ligaments & Bruises.

Contains Essential Oils and Natural Extracts

MSM Arnica Boswellia Ilex

Active Ingredient: Menthol

1 Gallon 128 fl. oz 4.2L



Pain Relieving Cold Therapy

GEL

Fast Acting, Penetrating Pain Relief For:
Muscle Strains, Joint Pain, Backache, Arthritis, Sprained Ligaments & Bruises.

Paraben Free / Propylene Glycol Free
Aspirin Free / NSAID Free
Silicon Dioxide Free / Gluten Free

Contains Essential Oils and Natural Extracts
MSM • Arnica • Boswellia • Ilex

Active Ingredient: Menthol

1 Gallon • 128 fl. oz. • 4.2L



Pain Relieving Cold Therapy

GEL

Drug Facts	
Active Ingredient Menthol USP 10.0%	Purpose Pain Reliever
Uses: Temporarily relieves minor aches and pains associated with • sore muscles and joints • arthritis • backache • muscle strains • sprains • bruises	
Warnings: For external use only	
When using this product: Use only as directed • Do not bandage or cover the area being treated • Do not apply ice or heating pad in conjunction with this product • Do not use with any medical device or other device • Do not combine with any other topical treatments • Avoid contact with eyes or mucous membrane • Do not apply to wounds or damaged skin	
Stop use and ask a doctor if: Condition worsens or symptoms persist for more than 7 days or clear up and recur • Redness is present or irritation develops	
If Pregnant or Breast Feeding: Ask a healthcare professional before use	
Keep Out of Reach of Children: In case of accidental ingestion get medical help or contact a Poison Control Center immediately	
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NDC # 68678-051-38

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Pain Relieving Cold Therapy

GEL



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PAIN RELIEVING COLD THERAPY

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68678-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68678-051-38	4.2 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part348	01/01/2016	

Labeler - AHC VENTURES CORP DBA CRYODERM (131871779)

Revised: 5/2022

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